DEC 9 2005

CO53258
HITACHI
Basic Information

4.2.1	Manufacturers Name (Ultrasound Scanner):	Hitachi Medical Corporation	
	Address:	Hitachi Kamakurabashi Bldg., 1-1-14 Uchi-kanda, Chiyoda-ku Tokyo 101-0047 Japan	
	Corresponding Official:	 Doug Thistlethwaite Manager, Regulatory Affairs 	
	Address:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087	
	<u>Telephone:</u>	(330) 425-1313	
4.2.2	Initial Distributor (Ultrasound Scanner):	Hitachi Medical Systems America, Inc.	
٠	Address:	1959 Summit Commerce Park Twinsburg, Ohio 44087	
	Telephone:	(330) 425-1313	
4.2.3	Device Name:	EUB-6500 Diagnostic Ultrasound Scanne	r
4.2.4	Common Name:	Diagnostic Ultrasound Unit	
4.2.5	Classification		
	Regulatory Class:	Class II	
	Review Category:	Tier II	
		FR Number	Product Codes
			10000
	Ultrasonic Pulsed Echo and Pulsed Doppler Imaging System	892.1550	90-IYN
426	Imaging System Diagnostic Ultrasound Transducer	892.1550 892.1570	90-IYN
4.2.6	Imaging System	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405	90-IYN 90-ITX
	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number:	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U	90-IYN 90-ITX
4.2.7	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number: 514 Performance Standards:	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U	90-IYN 90-ITX SA) 1528028
4.2.7	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number: 514 Performance Standards: Special Controls:	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U None Special Report – to be filed at a later date	90-IYN 90-ITX SA) 1528028
4.2.7 4.2.8 4.2.9	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number: 514 Performance Standards: Special Controls: Prescription Status:	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U None Special Report – to be filed at a later date Prescription Device	90-IYN 90-ITX SA) 1528028
4.2.7	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number: 514 Performance Standards: Special Controls:	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U None Special Report – to be filed at a later date	90-IYN 90-ITX SA) 1528028
4.2.7 4.2.8 4.2.9	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number: 514 Performance Standards: Special Controls: Prescription Status: Manufacturing Location (Ultrasound)	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U None Special Report – to be filed at a later date Prescription Device Hitachi Medical Corporation - Kashiwa Wo 2-1 Shintoyofuta Kashiwa-shi, Chiba-ken	90-IYN 90-ITX SA) 1528028
4.2.7 4.2.8 4.2.9 4.2.10	Imaging System Diagnostic Ultrasound Transducer Establishment Registration Number: 514 Performance Standards: Special Controls: Prescription Status: Manufacturing Location (Ultrasound Scanner):	892.1550 892.1570 Hitachi Medical Corp. (Japan) 8030405 Hitachi Medical Systems America, Inc. (U None Special Report – to be filed at a later date Prescription Device Hitachi Medical Corporation - Kashiwa Wo 2-1 Shintoyofuta Kashiwa-shi, Chiba-ken 277-0804 Japan	90-IYN 90-ITX SA) 1528028





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

DEC 9 2005

Hitachi Medical Corporation % Mr. Doug Thistlewaite Manager, Regulatory Affairs Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park TWINSBURG OH 44087

Re: K053258

Trade Name: EUB-6500 Diagnostic Ultrasound Scanner

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulatory Name: Ultrasonic pulsed echo imaging system

Regulatory Number: 21 CFR 892.1570

Regulatory Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: November 14, 2005 Received: November 22, 2005

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the EUB-6500 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

<u>EUP-B514</u> EUP-C312T EUP-C314G EUP-C511

EUP-C516	<u>EUP-L65</u>
EUP-C524	EUP-O53T
EUP-C532	<u>EUP-R54A-19</u>
EUP-CC531	<u>EUP-R54A-33</u>
EUP-CV524	<u>EUP-R54AW-19</u>
EUP-F334	<u>EUP-R54AW-33</u>
EUP-L34T	<u>EUP-S50</u>
EUP-L52	<u>EUP-S50A</u>
EUP-L53	<u>EUP-S52</u>
EUP-L53L	<u>Fujinon SP711</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Vancy Chrogelon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System:

EUB-6500

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	nical Application	Τ				le of Operati		
General (Track I only)		В	M	PWD	CWD	Color Doppler	Combined*	Other** (Spec.)
Ophthalmic	Ophthalmic	T				- spp.or	(Орес.)	(Dpec.)
	Fetal	P	P	P	Р	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)	P	P	Р		P	P	P
	Laparoscopic	P	P	P		P	P	- <u>1</u> P
	Pediatric	P	P	P	P	P	$\frac{1}{P}$	- <u>-</u> -
	Small Organ (Spec.)	Pd	Pd	Pd	-+	Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
Fetal Imaging	Adult Cephalic	P	P	P	P	P	P	- <u>1</u> P
& Other	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							11
	Trans-esoph. (non-Card.)					-		
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	$\frac{1}{P}$	- <u>1</u> P
i	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	P	P
Cardiac	Cardiac Pediatric	P	P	P	P	P	$\frac{1}{P}$	P
	Trans-esophageal (card.)	Pg	Pg	Pg		Pg	Pg	
	Other (spec.)					<u> </u>	1g	Pg
Peripheral	Peripheral vessel	Р	P	P	P	P	P	P
Vessel	Other (spec.)				- -		- 1	ľ

P = Previously Cleared, K013723

Additional Comment	s:
--------------------	----

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(meruding amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures)
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of him
Subscript "e":	merades imaging for guidance of transpectal bioney
Subscript "f":	Includes imaging for guidance of transvaginal bionsy
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE CONTROL

T WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT; and Radiological Devices

Prescri	ption	Use	?		
	[

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-6500

Transducer:

EUP-B514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)		В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	E	Е	E		Е	E	E	
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea	
	Intra-operative (Spec.)								
	Intra operative (Neuro.)					***************************************			
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
Fetal Imaging									
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
İ	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
	Peripheral vessel		-						
Vessel	Other (spec.)								

E = Added under Appendix E

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Ibivision Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

and Kadiological Devices

510(k) Number: <u>K053358</u>

Prescription	Use	_	

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-C312T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Intended use: Diagnostic ultrasound imaging Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
	Ophthalmic						1	E
	Fetal	Е	E	E		E	E	Ea
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)						 	
	Intra-operative (Neuro.)				<u> </u>			
	Laparoscopic			ļ			10	E
	Pediatric	Е	Е	E		E	E	Ed
	Small Organ (Spec.)	Ed	Ed	Ed	L	Ed	Ed	Eu
	Neonatal Cephalic				11			
Fetal Imaging	Adult Cephalic	_		<u> </u>				
& Other	Trans-rectal				ļi		 	
	Trans-vaginal			<u> </u>	L			
	Trans-urethral			<u> </u>	<u> </u>			
	Trans-esoph. (non-Card.)			<u> </u>	ļ ļ			
	Musculo-skel. (Convent.)		<u> </u>	<u> </u>				
	Musculo-skel. (Superfic.)		<u> </u>	<u> </u>	ļi			
	Intra-luminal			<u> </u>				
	Other (spec.)		ļ					
	Cardiac Adult							
Cardiac	Cardiac Pediatric		<u> </u>				<u> </u>	
	Trans-esophageal (card.)		<u> </u>					
	Other (spec.)			<u> </u>			ļ	
Peripheral	Peripheral vessel							
Vessel	Other (spec.)		<u> </u>	<u> </u>				<u> </u>

E = Added under Appendix E

Additional Com	iments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid parathyroid breast scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Carl assist the	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: <u>K0532</u>3

Prescription V	'Ise	
1		

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-C314G

tic ultrasound imaging or fluid flow analysis if the human body as follows:

ntended use: Diagnostic ultrasound imagi Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic					10	E	E		
	Fetal	E	E	E		E	Ea	Ea		
	Abdominal	Ea	Ea	Ea	 	Ea	Ea	La		
	Intra-operative (Spec.)						 			
	Intra-operative (Neuro.)			 _	ļi					
·	Laparoscopic			<u> </u>		15	E	E		
	Pediatric	E	E	E		E	Ed	Ed		
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Eu	120		
	Neonatal Cephalic			<u> </u>			<u> </u>			
Fetal Imaging	Adult Cephalic			↓			 			
& Other	Trans-rectal		<u> </u>	 			 			
	Trans-vaginal		<u> </u>	ļ	ļ		ļ			
	Trans-urethral		<u> </u>				 			
	Trans-esoph. (non-Card.)			 			<u> </u>			
	Musculo-skel. (Convent.)	L	<u> </u>	<u> </u>	ļ					
	Musculo-skel. (Superfic.)		<u> </u>		<u> </u>					
	Intra-luminal									
	Other (spec.)				<u> </u>		-			
	Cardiac Adult			⊥				ļ <u>-</u>		
Cardiac	Cardiac Pediatric	l		<u> </u>	ļ	<u> </u>		ļ		
	Trans-esophageal (card.)		<u> </u>	ļ	 					
	Other (spec.)	<u> </u>	<u> </u>		ļ	ļ		 		
Peripheral	Peripheral vessel				 					
Vessel	Other (spec.)			<u> </u>	<u> </u>					

E = Added under Appendix E

Additional Con	iments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
Duoboripe	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Included the maid narethyroid breast scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Rivision Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: ___

Prescription Use___

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-6500

Transducer:

EUP-C511

use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
	Ophthalmic					ъ	Ē	E		
	Fetal	E	E	E		E	Ea	Ea		
l	Abdominal	Ea	Ea	Ea	ļ	Ea	+ -Ea	110		
	Intra-operative (Spec.)				ļ <u>-</u>		 			
	Intra-operative (Neuro.)			↓	<u> </u>		 			
-	Laparoscopic			<u> </u>	 	E	E	E		
	Pediatric	Ε	E_	E		E	12			
	Small Organ (Spec.)		<u> </u>	 	<u> </u>					
	Neonatal Cephalic			 	<u> </u>		 			
Fetal Imaging	Adult Cephalic		ļ	 			_			
& Other	Trans-rectal		ļ		 		+			
	Trans-vaginal		 	ļ			 			
	Trans-urethral		ļ <u>.</u>	↓						
	Trans-esoph. (non-Card.)		<u> </u>	 	ļ	ļ 				
	Musculo-skel. (Convent.)		ļ	_	 	<u> </u>				
	Musculo-skel. (Superfic.)		_		<u> </u>					
	Intra-luminal		<u> </u>		 			 		
	Other (spec.)			 		10	E	E		
	Cardiac Adult	E	E	E	 	<u>Е</u> Е	+ -E	<u>E</u>		
Cardiac	Cardiac Pediatric	Е	E	E		<u> </u>	<u> </u>			
	Trans-esophageal (card.)				ļ		 	 		
	Other (spec.)		<u> </u>				E	Е		
Peripheral	Peripheral vessel	Е	E	E	 -	E	<u> </u>	<u> </u>		
Vessel	Other (spec.)				1	<u> </u>		<u> </u>		

E = Added under Appendix E

Additional Con	iments:
Subscript "a":_	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
Dubscript 0	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	T 1 1 the side constitution of breast scrotum penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of olopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
C 1 + +11 !!!	Includes imaging for guidance of transrectal biopsy. Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT.

and Radiological Devices

	▼
Crescription	Tise

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-C516

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	Е	E	E		Ė	E	E	
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea	
	Intra-operative (Spec.)			<u> </u>					
	Intra-operative (Neuro.)								
	Laparoscopic							- 13	
	Pediatric	Е	Е	E		E	E	E	
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed	
	Neonatal Cephalic			<u> </u>					
Fetal Imaging	Adult Cephalic								
& Other	Trans-rectal						1		
	Trans-vaginal		<u> </u>	<u> </u>			_		
	Trans-urethral			ļ	ļ ļ				
	Trans-esoph. (non-Card.)			<u> </u>					
	Musculo skel. (Convent.)				1				
	Musculo-skel. (Superfic.)				ļ		ļ		
	Intra-luminal						<u> </u>		
	Other (spec.)								
	Cardiac Adult		<u> </u>						
Cardiac	Cardiac Pediatric		<u> </u>						
	Trans-esophageal (card.)		<u> </u>						
	Other (spec.)					<u> </u>			
Peripheral	Peripheral vessel								
Vessel	Other (spec.)		1	1		<u> </u>			

E = Added under Appendix E

Additional Con	nments-
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
7	TO NOT WITH DELOW WHICH THE COMMINUE ON ANOTHER DACE IF MEEDED)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT; and Radiological Devices

510(k) Number: <u>K053258</u>

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-C524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	E	E	E		E	Ē	E	
	Abdominal	E	E	Е		E	E	Е	
•	Intra-operative (Spec.) Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric	E	E	E		E	E	E	
	Small Organ (Spec.)	E	E	E		E	Е	Е	
	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic							 -	
& Other	Trans-rectal			<u> </u>					
	Trans-vaginal		L	<u> </u>			ļ		
	Trans-urethral		<u> </u>	<u> </u>					
	Trans-esoph. (non-Card.)						 		
	Musculo-skel. (Convent.)		<u> </u>		<u> </u>				
	Musculo-skel. (Superfic.)								
	Intra-luminal		<u> </u>						
	Other (spec.)								
	Čardiac Adult		<u> </u>						
Cardiac	Cardiac Pediatric		<u> </u>						
	Trans-esophageal (card.)		<u> </u>				 		
	Other (spec.)								
Peripheral	Peripheral vessel				<u> </u>				
Vessel	Other (spec.)	L		1			1	<u> </u>	

E = Added under Appendix E

Additional Con	nments
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number:___

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-6500

Transducer:

EUP-C532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
		D	B M PWD CWD Color Combined* Other*							
General (Track I only)	Specific (Tracks I & III)	В	IVI	PWD	CWD	Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic						ļ			
	Fetal									
	Abdominal	Еa	Ea	Ea_		Ea	Ea	Ea		
	Intra operative (Spec.)	Eb	Eb	Eb		Eb	Eb	Eb		
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric	Ë	E	E		Е	Е	E		
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed		
	Neonatal Cephalic	E	E	E		E	E	E		
Fetal Imaging	Adult Cephalic						_			
& Other	Trans-rectal									
	Trans-vaginal									
	Trans-urethral	Ĭ		I						
	Trans-esoph. (non-Card.)						<u> </u>			
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)			Ī						
	Intra-luminal						ļ			
	Other (spec.)						·			
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel	Е	Е	E		E	Е	Е		
Vessel	Other (spec.)									

E = Added under Appendix E

Additional Com	ments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
<u> </u>	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	E DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: <u>L05325</u>

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-CC531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal Abdominal	Е	Ē	E		E	E	Е		
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic	- 1	<u> </u>	13.	\vdash	Ee	Ee	Ee		
& Other	Trans-rectal	Ee	Ee	Ee	<u> </u>	Ef	Ef	Ef		
,	Trans vaginal	Ef	Ef	Ef		Eil	121	151		
	Trans-urethral			 -						
	Trans-esoph. (non-Card.)				 					
	Musculo-skel. (Convent.)			ļ	ļ					
	Musculo-skel. (Superfic.)			<u> </u>			<u> </u>			
	Intra-luminal		<u> </u>							
•	Other (spec.)		<u> </u>		<u> </u>					
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)		1							
Peripheral	Peripheral vessel									
Vessel	Other (spec.)			<u> </u>		 -				

E = Added under Appendix E

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d"	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: ____

KO53258

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-CV524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal	N	N	N	N	N	N	N			
	Abdominal	N	N	N	N	N	N	N			
	Intra-operative (Spec.) Intra-operative (Neuro.)										
	Laparoscopic						<u> </u>				
	Pediatric	N	N	N	N	N	N	N			
	Small Organ (Spec.)	N	N	N	N	N	N	N			
	Neonatal Cephalic		<u> </u>				1				
Fetal Imaging	Adult Cephalic										
& Other	Trans-rectal										
	Trans-vaginal			ļ							
	Trans-urethral						ļ				
	Trans-esoph. (non-Card.)		ļ	<u> </u>			<u> </u>				
	Musculo-skel. (Convent.)		_	 	l						
	Musculo-skel. (Superfic.)		ļ		ļ						
	Intra-luminal		<u> </u>	ļ							
	Other (spec.)		1		-						
	Cardiac Adult		ļ	<u> </u>							
Cardiac	Cardiac Pediatric		<u> </u>								
	Trans-esophageal (card.)			_	↓						
	Other (spec.)		<u> </u>	 	1 -						
Peripheral	Peripheral vessel		ļ <u>.</u>		↓			-			
Vessel	Other (spec.)		<u> </u>				<u> </u>				

N = new indication.

Additional Con	nments
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Oney C Mondon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: <u>K053258</u>

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-6500

Transducer:

EUP-F334

tic ultrasound imaging or fluid flow analysis if the human body as follows:

	Diagnostic ultrasound imagi	ng or i	uia Ho	w anaiy	SIS II UIIE	la of Operati	on.	·········			
Clin	Clinical Application			Mode of Operation R M PWD CWD Color Combined* Other**							
General (Track I only)	Specific (Tracks I & III)	В	M 	PWD	CWD	Color Doppler	(Spec.)	(Spec.)			
Ophthalmic	Ophthalmic	L									
Fetal Imaging & Other	Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	Eb Ec Ec E	Eb E Ec E E	Eb E Ec E E		Eb Ec Ec E	Eb Ec Ec E	Eb Ec E E			
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)										
Peripheral Vessel	Peripheral vessel Other (spec.)	_ E	Е	Е		E	E	Е			

E = Added under Appendix E

Additional Com	uments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
/DI EAC	VE DO NOT WRITE DELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-L34T

gnostic ultrasound imaging or fluid flow analysis if the human body as follows:

			Mode of Operation							
	ical Application	7.)	3.4	LDWD		Color	Combined*	Other**		
General	Specific	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)		
(Track I only)	(Tracks I & III)			<u> </u>		Dobbier	(Брес.)	Орсс.		
Ophthalmic	Ophthalmic									
	Fetal			<u> </u>		ъ.	IZ-	Ea		
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea		
	Intra-operative (Spec.)			<u> </u>						
	Intra-operative (Neuro.)			ļ	ļļ					
	Laparoscopic			<u> </u>			10	Ė		
	Pediatric	E	E	E	<u> </u>	E	E	Ed		
,	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed		
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic			<u> </u>			ļ			
& Other	Trans-rectal						ļ.————			
	Trans-vaginal		<u> </u>	<u> </u>						
	Trans-urethral									
	Trans-esoph. (non-Card.)				L					
	Musculo-skel. (Convent.)	E	E	Е	ļļ	Ē	E	E		
	Musculo-skel. (Superfic.)	E	Е	E		Е	E	Ē		
	Intra-luminal			<u> </u>	<u> </u>		<u> </u>			
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)				1					
	Other (spec.)			<u></u>						
Peripheral	Peripheral vessel	E	Е	Е		E	E	É		
Vessel	Other (spec.)		ļ				<u> </u>			

E = Added under Appendix E

Additional Con	iments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
<u> </u>	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
TOT TO A S	EE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division (Fign-Off))
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP·L52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal Abdominal Intra-operative (Spec.)	Ea	Ea	Ea		Ea	Ea	Ea		
	Intra operative (Neuro.) Laparoscopic									
	Pediatric	E	Е	E		E	E	E		
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed		
	Neonatal Cephalic									
Fetal Imaging										
& Other	Trans-rectal									
	Trans-vaginal				li					
	Trans-urethral									
	Trans-esoph. (non-Card.)		ļ <u> </u>							
	Musculo-skel. (Convent.)	E	E	Е		Е	E	E		
	Musculo-skel. (Superfic.)			<u> </u>			<u> </u>			
	Intra-luminal			<u> </u>			 			
	Other (spec.)			<u> </u>						
	Cardiac Adult			<u> </u>			1			
Cardiac	Cardiac Pediatric			<u> </u>	11		<u> </u>			
	Trans-esophageal (card.)		_				4			
	Other (spec.)									
Peripheral	Peripheral vessel	E	Е	Е	ļ	E	Ē	E		
Vessel	Other (spec.)			<u> </u>						

E = Added under Appendix E

A 1 1141	l Comments	
MAGNITIONSI	Lomments	٠.

, indicional con	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: ____

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-L53

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal Abdominal Intra operative (Spec.) Intra operative (Neuro.)	Ea	Ea	Ea		Ea	Ea	Ea		
	Laparoscopic Pediatric Small Organ (Spec.)	E Ed	E Ed	E Ed		E Ed	E Ed	E Ed		
Fetal Imaging & Other	Trans-rectal									
	Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.) Musculo-skel. (Superfic.)	E E	E E	E		E E	E E	E E		
	Intra-luminal Other (spec.)									
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.)									
Peripheral Vessel	Other (spec.) Peripheral vessel Other (spec.)	Е	Е	E		E	E	Е		

E = Added under Appendix E

Additional Comments:

Subscript "a"	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
-	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d"	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g"	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, EN

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-6500

Transducer:

EUP·L53L

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.)	Е	Е	Е		E	E	E		
	Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic	E Ec	E Ec	E Ec		E Ec	E Ec	E Ec		
Fetal Imaging & Other	Adult Cephalic Trans-rectal									
	Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal	E E	E	E		E E	Ē E	E		
Cardiac	Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)	Е	Е	Е		Е	Е	E		

E = Added under Appendix E

Additional	Comments:

riaditional Con	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
<u> </u>	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
	The state of the s

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-L65

tic ultrasound imaging or fluid flow analysis if the human body as follows:

	ing or fluid flow analysis if the numan body as follows:									
Clin	ical Application	Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic			Ĭ						
	Fetal Abdominal Intra-operative (Spec.)	E	E	Е		E	Е	E		
	Intra operative (Neuro.) Laparoscopic Pediatric	Е	E	E		E	Ē	Е		
	Small Organ (Spec.) Neonatal Cephalic	Ec	Ec	Ec		Ec	Ec	Ec		
Fetal Imaging & Other	Adult Cephalic Trans-rectal									
	Trans-vaginal Trans-urethral	<u> </u>								
	Trans-esoph. (non-Card.) Musculo-skel. (Convent.)	E	E	E		Е	E	E		
	Musculo-skel. (Superfic.) Intra-luminal	E	E	E		Е	E	E		
<u> </u>	Other (spec.) Cardiac Adult		<u> </u>	 	├					
Cardiac	Cardiac Pediatric Trans-esophageal (card.)									
Peripheral	Other (spec.) Peripheral vessel	E	E	E		E	E	E		
Vessel	Other (spec.)	ы	, i.i							

E = Added under Appendix E

Additional Comments:

-

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-O53T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult	Eb	Eb	Eb		Eb	Eb	Ëb		
Cardiac	Cardiac Addit Cardiac Pediatric Trans-esophageal (card.) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)									

E = Added under Appendix E

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number:____

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-R54A-19

Intended use. Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		ing or fluid flow analysis if the human body as follows. Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic	E	E	E		E	E	E		
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)									

E = Added under Appendix E

Additional Con	nments:	
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures	_
	(including amniocentesis).	_
Subscript "b":	Includes imaging of organs and structures exposed during surgery	
	(excluding neurosurgery and laparoscopic procedures).	
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.	_
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.	_
Subscript "e":	Includes imaging for guidance of transrectal biopsy.	_
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.	_
Subscript "g":	For pediatric patients.	_
C 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Y 1 1 i C wild-was of two parcetal biopage	

Subscript "h": Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-R54A-33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation								
		D	I M	PWD	CWD	Color	Combined*	Other**		
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Doppler_	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic									
:	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic				ļ					
Fetal Imaging	Adult Cephalic									
& Other	Trans rectal	E	E	Е		E	E	Е		
	Trans-vaginal		<u> </u>				<u> </u>			
	Trans urethral				<u> </u>					
	Trans-esoph. (non-Card.)		<u> </u>				1			
	Musculo-skel. (Convent.)		<u>L</u>							
	Musculo-skel. (Superfic.)			ļ <u>.</u>	L					
ı	Intra-luminal		ļ	ļ			ļ			
	Other (spec.)		<u> </u>	<u> </u>						
	Cardiac Adult			<u> </u>						
Cardiac	Cardiac Pediatric							<u></u>		
	Trans-esophageal (card.)		ļ							
	Other (spec.)			<u> </u>						
Peripheral	Peripheral vessel									
Vessel	Other (spec.)		<u>l</u>							

E = Added under Appendix E

Additiona	l Cor	nments:
Subscript	"a":	Include

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-R54AW-19

ded use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

ical Application Specific					de of Operati		
(Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic							
Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	E	E	E		E	E	E
Cardiac Pediatric Trans-esophageal (card.) Other (spec.)							
Peripheral vessel			-				
	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-usesoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal E Trans-vaginal Trans-urethral Trans-urethral Trans-urethral Convent.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel Other (spec.)	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel Other (spec.)	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel Other (spec.)	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal E E E Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel Other (spec.)	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal E E E E Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel Other (spec.)	Fetal

E = Added under Appendix E

Additional	Cammanta'

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "b"	Includes imaging for guidance of transrectal biopsy.
7DT 2240	GE DO NOT WRITE DELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: __

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-R54AW-33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	E	E	E		E	E	E	
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)								
Peripheral Vessel	Peripheral vessel Other (spec.)								

E = Added under Appendix E

Additional Con	iments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT;

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-S50

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic						<u></u>	Ê	
<u> </u>	Fetal	Е	Ē	E	E	E	E	Ea	
	Abdominal	Ea	Ea	Ea	Ea	Ea	Ea	Ea	
	Intra-operative (Spec.)			ļ			 		
	Intra-operative (Neuro.)			<u> </u>					
	Laparoscopic			<u> </u>			E	E	
	Pediatric	E	E	E	Е	E	- E	E	
	Small Organ (Spec.)				1				
	Neonatal Cephalic			<u> </u>			E	E	
Fetal Imaging		E	E	E	Е	Е	<u> </u>	<u> </u>	
& Other	Trans-rectal		<u> </u>		 				
	Trans-vaginal				ļ — ļ				
	Trans-urethral		<u> </u>	 	1 — 1				
	Trans esoph. (non-Card.)		<u> </u>	ļ	ļ		 		
	Musculo skel. (Convent.)		 	_	 		<u> </u>		
	Musculo-skel. (Superfic.)		<u> </u>						
	Intra-luminal		<u> </u>	ļ					
_	Other (spec.)					13	E	E	
	Cardiac Adult	E	E	E	E	<u>E</u>	E	E E	
Cardiac	Cardiac Pediatric	E	E	E	E	E	E	<u> </u>	
	Trans-esophageal (card.)			ļ <u>-</u>	_				
	Other (spec.)				ļ <u>.</u>		13	E	
Peripheral	Peripheral vessel	E	E	Е	E	E	Е	E	
Vessel	Other (spec.)		<u> </u>		<u> </u>	<u> </u>			

E = Added under Appendix E

iments:
Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
(including amniocentesis).
Includes imaging of organs and structures exposed during surgery
(excluding neurosurgery and laparoscopic procedures).
Includes thyroid parathyroid, breast, scrotum, penis.
Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Includes imaging for guidance of transrectal biopsy.
Includes imaging for guidance of transvaginal biopsy.
For pediatric patients.
Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number: __

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-6500 EUP-S50A

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
	Ophthalmic								
	Fetal	E	E	Е	Е	E	E	E	
	Abdominal	E	E	E	Е	E	E	Е	
	Intra-operative (Spec.)						<u> </u>		
	Intra-operative (Neuro.)		<u> </u>	<u> </u>					
	Laparoscopic		<u> </u>						
	Pediatric	Е	E	E	Е	E	E	E	
	Small Organ (Spec.)		<u> </u>						
	Neonatal Cephalic				<u> </u>				
Fetal Imaging	Adult Cephalic	E	Е	E	E	E	E	E	
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral		<u> </u>		ļļ				
	Trans-esoph. (non-Card.)						ļ		
	Musculo-skel. (Convent.)		<u> </u>				ļ		
	Musculo-skel. (Superfic.)			<u> </u>					
	Intra-luminal		<u> </u>				<u> </u>		
	Other (spec.)		<u> </u>						
	Cardiac Adult	E_	Е	E	E	E	E	E	
Cardiac	Cardiac Pediatric	E	E	E	E	E	E	Е	
	Trans-esophageal (card.)								
	Other (spec.)			1					
Peripheral	Peripheral vessel	Е	E	E	E	E	E	Е	
Vessel	Other (spec.)							<u> </u>	

E = Added under Appendix E

nments
Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
(including amniocentesis).
Includes imaging of organs and structures exposed during surgery
(excluding neurosurgery and laparoscopic procedures).
Includes thyroid, parathyroid, breast, scrotum, penis.
Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Includes imaging for guidance of transrectal biopsy.
Includes imaging for guidance of transvaginal biopsy.
For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT,

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

EUP-S52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M 	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
ı	Intra-operative (Spec.)			<u> </u>			ļ		
	Intra-operative (Neuro.)						<u> </u>		
	Laparoscopic			ļ				13	
	Pediatric	E	E	Е	Е	E	E	E	
	Small Organ (Spec.)	Ec	Ec_	Ec	Ec	Ec	Ec	Ec	
	Neonatal Cephalic			<u> </u>	 				
Fetal Imaging	Adult Cephalic				ļl				
& Other	Trans-rectal			ļ					
	Trans-vaginal								
	Trans-urethral		<u> </u>		<u> </u>		<u> </u>		
	Trans-esoph. (non-Card.)				ļl				
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)				11		<u> </u>		
	Intra-luminal			ļ			<u> </u>		
	Other (spec.)			<u> </u>					
	Cardiac Adult						ļ		
Cardiac	Cardiac Pediatric	Е	Е	E	E	E	Е	E	
	Trans-esophageal (card.)				1				
	Other (spec.)								
Peripheral	Peripheral vessel				ļ				
Vessel	Other (spec.)			<u> </u>	<u></u>		1	<u> </u>	

E = Added under Appendix E

Additional Con	nments:
Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-6500

Transducer:

Fujinon SP711

octic ultracound imaging or fluid flow analysis if the human body as follows:

		ing or fluid flow analysis if the numan body as follows: Mode of Operation							
Clinical Application									
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Doppler_	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	E							
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)								
Peripheral Vessel	Peripheral vessel Other (spec.)								

E = Added under Appendix E

Additional	Comments:
Additional	Comme.

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	For pediatric patients.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT;

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.